

Section. 5 510(k) Summary**JUN 24 2013**

Company Name: Cardiovascular Systems, Inc.
651 Campus Drive
Saint Paul, MN 55112

Contact: Maureen McDonnell

Phone: (651) 259-1644

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Summary Date: April 17, 2013

Trade Name: Stealth 360°® Orbital PAD System

Product Code: MCW—Catheter, Peripheral, Atherectomy

Classification: 21 CFR 870.4875—Intraluminal Artery Stripper

Predicate Device:

510(k) Number: K110389 & K122987
Manufacturer: Cardiovascular Systems, Inc.
Trade Name: Stealth 360°® Orbital PAD System

5.1 Description of Device

The Stealth 360° Orbital PAD System is an orbital atherectomy system (OAS) that is intended for use in the treatment of peripheral arteries and A-V graft (shunt) stenosis.

The OAS provides a method of removing stenotic material from peripheral arteries and A-V grafts. The Stealth 360° uses an electrically driven shaft to apply a diamond coated, eccentrically rotating sanding surface to ablate stenotic material. The stenotic particles that are removed are small enough to be absorbed by the body.

The Stealth 360° Orbital PAD System consists of the following components:

- 1) Orbital Atherectomy Device (OAD)
- 2) Atherectomy Guide Wire
- 3) Saline Infusion Pump (SIP)
- 4) Atherectomy Lubricant (e.g. ViperSlide)

5.2 Intended Use

The Stealth 360° Orbital PAD System is a percutaneous orbital atherectomy system indicated for use as therapy in patients with occlusive atherosclerotic disease in peripheral arteries and who are acceptable candidates for percutaneous transluminal atherectomy.

The OAS supports removal of stenotic material from artificial arteriovenous dialysis fistulae (AV shunt). The OAS is a percutaneous orbital atherectomy system indicated as a therapy in patients with occluded hemodialysis grafts who are acceptable candidates for percutaneous transluminal angioplasty.

5.3 Technology

The Stealth 360° Orbital PAD System provides a method of removing occlusive atherosclerotic or stenotic material. The OAS applies a diamond coated, eccentrically rotating sanding surface to ablate stenotic tissue. The stenotic particles that are removed are small enough to be absorbed by the body. This same technology was cleared to market for use in 510(k) K122987, K110389, K071350, and Predator 360° (originally cleared as 3X) per K090521.

The current printed circuit board assembly (PCBA) used in the OAD is developed and purchased externally. A CSI developed board was created that will allow for additional Input/Output (I/O) points to enable future expandability options. The modified device will use one of the additional I/O points to add a saline prime button to the device handle that functions in the same way as the existing prime button on the saline infusion pump. The instructions for use were updated to include information about use of the prime button on the OAD.

5.4 Performance Data

The modified Stealth 360° Orbital PAD System was evaluated using the following performance bench testing to confirm the performance characteristics as compared to the predicate device.

- Life/Stall Testint
- Orbit Testing
- Switch Logic/End of Life Testing
- Distribution Testing
- Shelf Life Testing
- ISO MEM Elution Assay
- ISO Intracutaneous Reactivity Test
- Electrical Safety Testing
- Electromagnetic Compatibility (EMC) Testing
- Firmware testing: Modular, Integration, Functional

All test results demonstrate that the materials chosen, the manufacturing process, and the design utilized for the Stealth 360° Orbital PAD System met the established specifications necessary for consistent performance during its intended use.

5.5 Conclusions

The Stealth 360° Orbital PAD System with the CSI developed PCBA met all predetermined acceptance criteria of design verification and validation testing as specified by applicable standards, test protocols, and/or customer inputs. Testing results demonstrate that the Stealth 360° Orbital PAD System with the CSI developed PCBA is substantially equivalent to the legally marketed predicate device and does not raise any new safety or effectiveness questions.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 24, 2013

Cardiovascular Systems, Inc.
c/o Ms. Maureen McDonnell
Sr. Regulatory Affairs Specialist
651 Campus Drive
St. Paul, MN 55112

Re: K131092
Trade/Device Name: Stealth 360° Orbital PAD System
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II
Product Code: MCW
Dated: June 3, 2013
Received: June 4, 2013

Dear Ms. McDonnell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. However, we remind you that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section. 4 Indications for Use Statement

510(k) Number: K131092

Device Name: Stealth 360°® Orbital PAD System

Indications for Use:

The Stealth 360° Orbital PAD System is a percutaneous orbital atherectomy system indicated for use as therapy in patients with occlusive atherosclerotic disease in peripheral arteries and who are acceptable candidates for percutaneous transluminal atherectomy.

The OAS supports removal of stenotic material from artificial arteriovenous dialysis fistulae (AV shunt). The OAS is a percutaneous orbital atherectomy system indicated as a therapy in patients with occluded hemodialysis grafts who are acceptable candidates for percutaneous transluminal angioplasty.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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